Claims 1-11, 13, 51-57, 59 and 61-62 were rejected under 35 USC 112, first paragraph, because the specification, while enabling for *Bacillus lentus subtilisin* variants does not, according to the Office Action, reasonably provide enablement for the scope of the instant claims. According to the Office Action, there is no indication as to why the Amidase/Esterase ratio is important. In addition, the Office Action indicates that there is no argument as to why the scope of the claims should be enlarged beyond *Bacillus lentus subtilisin.* These rejections are traversed for the reasons set forth herein.

Contrary to the assertion in the Office Action, the specification indicates that the Amidase/Esterase ratio is important for, among other reasons, variation of amino acid length (and assays to determine the Amidase/Esterase ratio are well-known in the art and provided in the specification at, for example, page 18, lines 19-20, et seq., inter alia).

Likewise, the full scope of the claims is enabled. An invention is enabled if one skilled in the art could make and/or use the claimed invention from the disclosure(s) in the patent application without undue experimentation (*see, e.g., MPEP 2164.01 and United States Telectronics, Inc.*, 857 F.2d 778, 8 USPQ2d 1217 (Fed Cir. 1988); *In Re Stephens*, 188 USPQ 659 (CCPA 1976). Whether undue experimentation is needed is based upon the following factors: 1) the quantity of experimentation needed (time and expense); 2) the amount of direction or guidance provided in the specification; 3) the presence or absence of working examples of the invention provided in the specification; 4) the nature of the invention; 5) the state of the prior art; 6) the relative skill of those in the art; 7) the predictability or unpredictability of the art; and 8) the breadth of the claims (*see In re Wands,* 8 USPQ2d 1400 (Fed. Cir. 1988).

In the instant case, the claims are drawn to a serine hydrolase. The specification need not teach one skilled in the art how to determine whether each embodiment within the scope of the claims is operable, as suggested by the Office Action. Rather, the specification must teach how to make/or use each embodiment within the scope of the claims without undue experimentation. And, since the specification teaches how to make *Bacillus lentus subtilsin* (and one skilled in the art using the specification as well as the art available at the filing date of the application could determine, case by case, whether each additional embodiment, each additional serine hydrolase, could be made and was operable), the specification is sufficient under 35 USC 112, first paragraph for each and every embodiment of the claimed invention. Accordingly, reconsideration and withdrawal of the rejections are proper and respectfully requested.

Claims 1-11, 13, 51-57, 59 and 61-62 were rejected under 35 USC 103(a), first paragraph, as being unpatentable over Berglund, et al. These rejections are traversed for the reasons set forth herein.

The Office Action indicates that: "It is well known that some chemical compounds are chiral and some are not and whether this limitation should make a difference in the allowability of the instant claims is a fact based matter. Berglund et al. (C2) states in the first paragraph that 'site-directed mutation...offers virtually unlimited possibilities for creating new structural environments at any enzyme location,' which it is maintained envisions both chiral and non-chiral compounds." Likewise, the Office Action provides "...it would have been obvious to one of ordinary skill in the art to modify enzymes as taught in the instant references and it would have been further obvious to use both chiral and non-chiral compounds in view of the well know (*sic*) fact that there (*sic*) both type (*sic*) compounds exist and in view of the statement mentioned *supra* in Berglund et al. (C2). The motivation would have been to produce mutant enzymes and to assay their properties."

To establish a *prima facie* case of obviousness, the prior art reference (or references when combined) must teach or suggest all the claimed limitations (*see*, inter alia, MPEP 2143 et seq; and In Re Vaeck 20 USPQ2d 1438 (Fed.Cir.1991)); there is no legal precedent to support a bald assertion in an Office Action that a reference may "envision" one of the claim limitations and establish a *prima facie* case with respect to the limitation. The present claims recite a chiral substituent, and the references, alone or together, do not teach or suggest a chiral substituent. Accordingly, the Office Action does not establish a *prima facie* case of obviousness, and reconsideration and withdrawal of the rejections are proper and respectfully requested.

Applicants would like to note that none of obviousness rejections recited in the Office Action provided any substantive basis (the burden of communicating the basis for the rejection is on the Examiner, *see* e.g., MPEP 2164.03, 2163.04, etc) and invite the Examiner to provide substance for the rejections, if available.

In view of the foregoing, Applicants believe all claims now pending in this application are in condition for allowance and issuance of a formal Notice of Allowance is respectfully requested. Examiner Patterson is invited to contact Applicants at (650) 846-7544 if there are additional questions/concerns.

Respectfully submitted,

Date: December 3, 2002

H. Thomas Anderton, Jr.
Registration No. 40,895

Genencor International, Inc.
925 Page Mill Road
Palo Alto, CA 94304-1013
Tel: 650-846-7544
Fax: 650-845-6504